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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,033

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Yaron Keidar

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EXAMINER

NEAL, TIMOTHY J

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/618,033

Applicant(s)

KEIDAR, YARON

Examiner

Timothy J. Neal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicant's amendment filed on 11/15/2006. Currently, claims 1-22 are pending, claims 1-19 are under consideration and claims 20-22 have been withdrawn from consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Kerr (US 2006/0079925).

Kerr discloses:

1. A device comprising: an elongated tubular body having an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough (Fig 9 Item 20); and a dilating tip slidably mounted on the distal end of the tubular body (Fig 9 Item 12a) and comprising a segmented surface that is generally transverse to the axis of the tubular body, and a generally rigid tube extending distally from the segmented surface and

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having a sharp distal end adapted to puncture tissue (Paragraph 57); wherein distal movement of the tubular body relative to the dilating tip exerts a force on the segmented surface to thereby open the segmented surface (Fig 9 and 10).

2. A device according to claim 1, wherein the elongated tube is generally cylindrical (Fig 9 Item 20).

3. A device according to claim 1, where the segmented surface comprises two or more segments (Fig 3).

4. A device according to claim 1, where the segmented surface comprises three or more segments (Fig 3).

5. A device according to claim 1, wherein the dilating tip further comprises a ring mounted in surrounding relation to the tubular body (Fig 10).

6. A device according to claim 5, wherein the segmented surface comprises a plurality of segments, each of which is hingedly attached to the ring (Fig 10).

7. A device according to claim 1, wherein the dilating tip is generally funnel-shaped (Fig 9 Item 26).

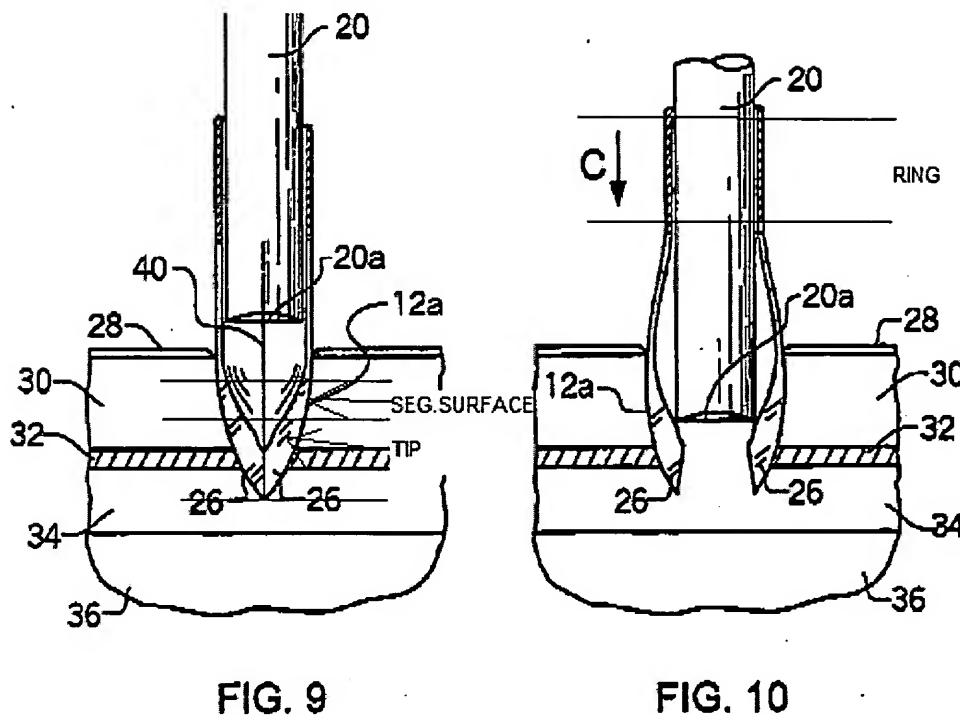
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8. A device according to claim 1, wherein the generally rigid tube of the dilating tip is segmented (Fig 9 Item 26).

18. A device comprising: an elongated tubular body having an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough (Fig 9 Item 20); a dilating tip slidably mounted on the distal end of the tubular body (Fig 9 Item 26) and comprising: a ring mounted in surrounding relation to the distal end of the tubular body (proximal portion of Item 12); a segmented surface that is generally transverse to the axis of the tubular body, the segmented surface comprising three or more segments, each segment being hingedly attached to the ring (Fig 9 and 10); and a generally rigid tube extending distally from the segmented surface (Fig 9 Item 26), the tube having a sharp distal end adapted to puncture tissue (Paragraph 57) and being segmented into three or more segments (Fig 3); wherein distal movement of the tubular body relative to the dilating tip exerts a force on the segmented surface and the generally rigid tube to thereby open the segmented surface and the generally rigid tube (Fig 9 and 10).

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Examiner Mark-up Drawings for Kerr '925:

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerr '925.

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Kerr discloses the invention substantially as claimed as stated above. Kerr does not explicitly disclose the claimed lengths and diameters of the generally rigid tube of the dilating tip. However, the Examiner considers it within the purview of one having ordinary skill in the art to modify a device's length and diameter to meet the desired sizes for a given application. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Kerr's dimensions to include those of the claims. Such a modification would be necessary for the device to be used in certain applications.

Kerr also does not explicitly disclose the use of nitinol for the tip. However, the Examiner considers it to be old and well known in the art to use nitinol in a variety of applications because it is biocompatible. Kerr discloses the use of biologically compatible alloys for use with his invention (Paragraph 15). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Kerr's tip to include nitinol. Such a modification would provide a well-known alloy with desirable biocompatibility.

Claims 14-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerr '925 in view of Wallace et al. (US 6,254,628).

Kerr discloses the invention substantially as claimed as stated above. Kerr does not explicitly disclose a wire extending proximally from the dilating tip to near the proximal end of the tubular body to effect proximal movement of the dilating tip relative to the tubular body and a slidable member on the proximal end of the tubular body, the

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slidable member being connected to the wire so that proximal movement of the slidable member pulls the wire and causes the proximal movement of the dilating tip relative to the tubular body. Wallace teaches the concept of controlling the distal movement of a retractable or sliding element from the proximal end of the device (Fig 28-34). Wallace teaches a pull tab connected to a pull wire that is connected to a pulling control mechanism on the proximal end of the catheter (Col 18 Line 66 through Col 19 Line 3). Therefore, it would have been obvious to a person having ordinary skill in the art to modify Kerr's device to include Wallace's pull wire and proximal member. Such a modification would allow the operator to manipulate the action of the distal tip from a location proximal to the tip, possibly outside the body.

Kerr and Wallace disclose the invention substantially as claimed. They do not disclose a latch for maintaining the position of the slidable member. However, the Examiner considers latches to be known for selectively maintaining the position of a wide variety of elements. Therefore, it would have been obvious to a person having ordinary skill in the art to modify Kerr and Wallace's device to include a latch mechanism for maintaining the position of the slidable member. Such a modification would prevent the tip from undesirably opening. It gives the operator control over the opening and closing of the distal tip. If the tip opens prematurely, damage will occur to the surrounding tissue.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kerr '925 in view of Devos et al. (US 6,099,511).

Kerr discloses the invention substantially as claimed as stated above. Kerr does not disclose a pressure valve at or near the proximal end of the tubular body. Devos teaches a pressure valve at or near the proximal end of the tubular body (Fig. 1 Item 30). Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Kerr's apparatus to include Devos's pressure valve. Such a modification would be to measure different pressures in a catheterized heart.

Response to Arguments

Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argued that the reference of the prior action (Selmon et al. US 6,217,549) did not disclose a sharp distal tip. The Examiner considers the Kerr reference to disclose the sharp distal tip. The tip does not need to be adapted specifically to puncture tissue, but only needs to be capable of puncturing tissue. Because the reference discloses the tip to be sharp, the Examiner considers the tip to be capable of puncturing tissue. Without further limiting the relation between the segmented surface, the rigid tube, and the elongated tubular body, the Examiner considers Kerr to read on the claims. "Transverse" as recited in claim 1 does not exclude Kerr because it only requires that the segmented surfaces are crosswise to the tubular body, not perpendicular. Because the Examiner can interpret the rigid tube and segmented surface broadly, the sizes recited in the claims are considered obvious.

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The combination of the Kerr reference with the Wallace reference teaches the concept of using proximal controls to manipulate the distal end of a device. The device of Wallace is sufficiently similar to that of Kerr, that the Examiner considers the reference to be analogous art. Also, the Wallace reference is directed at a similar problem solving area as the Applicant's claimed limitation. Therefore, the Examiner considers the combination of the references to be acceptable. Furthermore, because the claims do not recite any specific structure for the slidable member, the Examiner considers the pulling control mechanism to read on a slidable member.

Latches are well known in many fields for maintaining the position of a variety of elements. For example, latches have been used on doors to prevent the door from inadvertently swinging open or becoming dislodged. Although a door is not analogous art, the use of a latch is directed at the same problem-solving endeavor as the Applicant's latch. Without further limiting the relation between the latch and the slidable member or more specific structure of the latch, the Examiner considers the use of a latch as generally claimed to be obvious to one having ordinary skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

1/19/52